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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,176	12/13/2000	Josef V. Koblish	15916-279	8413

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/737,176	KOBLISH ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-16,18-28,33,36,37,39 and 41-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,4,6-16,18-28,33,36,37 and 49* is/are allowed.

6)☒ Claim(s) *39,41-48 and 50-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2004 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 39, 41-48 and 50-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Independent claims 39 and 54 each specifically recites that the therapeutic element "causes tissue to be heated". This is a positive recitation of tissue, which is non-statutory subject matter. It is suggested the language be amended to recite that the therapeutic device is "adapted to cause tissue to be heated" to avoid the positive inclusion of tissue in the claim language.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 41-48 and 50-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's positive recitation of "tissue" makes unclear the scope of the claim (see previous 35 USC 101 rejection).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39, 41-43 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab ('392) in view of the teachings of Campbell et al ('483) and/or Burton et al ('271).

Saab discloses a surgical probe which includes a relatively short shaft (66) having distal and proximal portions, and an inflatable, energy transmitting therapeutic element (72) at the distal end. An infusion lumen (64) and a ventilation lumen (68) extend proximally from the inflatable member and there is a source of cooling fluid connected to the probe and adapted to maintain pressure and continuously infuse and vent the cooling fluid (col. 7, lines 5-20). Various heating options are available, as well as simultaneous heating while cooling (col. 11, lines 12-45). There is no perfusion of the fluid through the balloon surface. Saab fails to expressly state that the balloon "causes tissue to be heated" as now set forth, and applicant contends that the Saab balloon segment is not the structure that is causing the heating of tissue and that the

relative placement of heating probes (i.e. microwave, laser, ultrasound, etc.) is not specifically shown.

The examiner maintains that the use of such heating devices (i.e. microwave, laser, etc.) within a balloon, and specifically within a cooled balloon, is generally well known in the art. In particular, Campbell et al and Burton et al both disclose balloon devices which house a heating member, the balloon being provided with a cooling fluid to cool the tissue surface immediately adjacent the balloon to allow heating of deeper targeted tissues.

Applicant contends that it is the probe within the balloon, and not the balloon, per se, which heats tissue. While the examiner generally agrees with this characterization, it is the examiner's position that the prior art (including Saab) still reads on the claim language which recites the therapeutic element "causes tissue to be heated". In Saab, as well as in Campbell et al and Burton et al, the heating means is located within the balloon (i.e. therapeutic element) and heats tissue. The claim does not require the heat to emanate from any specific area of the balloon that would preclude the application of the cited references to the claim language. That is, the heat is emanating from within each of the balloons in the Saab, Campbell et al and Burton et al devices and therefore the balloon is considered to be causing the tissue to be heated.

In summary, it is deemed to be an obvious consideration for one of ordinary skill in the art to have provided the Saab system with a heating device within the treatment balloon, which balloon includes a continuously infused cooling fluid, to allow for the treatment of deeper targeted tissue while preventing injury to tissue immediately in

contact with the balloon, particularly in view of the teachings of Campbell et al and Burton et al.

Claims 50 and 53 are rejected under 35 U.S.C. 103(a) as being anticipated by Stern et al ('470) in view of the teaching of Saab ('392).

Stern et al discloses a probe which includes a relatively short, relatively stiff shaft for treating the uterine cavity. The probe has a distal portion including a means for inflating and transmitting current to tissue at a level sufficient to cause lesions. The inflating means is a balloon (14) which includes RF energy delivery means to deliver ablative energy to tissue. The balloon does not allow perfusion of fluid through the balloon surface. There is no specific teaching of continuously infusing and ventilating the cooling fluid to/from the balloon.

As addressed previously, Saab teach that it is known to provide a continuously infused and ventilated balloon for circulating a fluid through a balloon and maintaining pressure in the balloon. With regard to the cooling function, continuous ventilation and infusion allows for better thermal properties to cool the surface of the balloon to prevent damage to tissue in contact with the balloon while allowing treatment of deeper targeted tissues.

To have provided the Stern et al balloon with a means to continuously infuse and ventilate a fluid to provide superior cooling capabilities and prevent damage to tissue in contact with the balloon would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Saab.

Claims 44 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab ('392), Campbell et al ('483) and Burton et al ('271) as applied to claims 39, 41-43 and 54-57 above, and further in view of the teaching of Deslauriers et al ('678).

Saab fails to specifically disclose the probe as having a malleable property to allow for the shaping of the device prior to insertion to more effectively conform to a tissue treatment area.

Deslauriers et al disclose a balloon device which includes a probe shaft with an inflatable balloon at the distal portion similar to the Saab device. In particular, Deslauriers et al teach that it is advantageous to provide the shaft as a malleable member to facilitate its insertion into the body passage and to conform to the desired tissue site.

To have provided the Saab probe, as modified by the teachings of Campbell et al and Burton et al, with a malleable shaft to facilitate its insertion into a body cavity and to conform to the shape of the desired treatment area would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Deslauriers et al.

Claims 46-48 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab ('392), Campbell et al ('483) and Burton et al ('271) and further in view of the teaching of Abele ('311).

As addressed previously, Saab provides a means to continuously infuse and ventilate a cooling fluid into a balloon to maintain a desired pressure (col. 7, lines 5-20). However, Saab fails to specifically disclose the use of a pressure sensor to determine the pressure in the balloon and control the delivery of fluid to maintain a desired pressure.

Abele et al disclose an analogous device which includes a probe having an inflatable member at the distal end and means for effecting thermal transfer to tissue via the inflatable member. More specifically, Abele et al teach that it is known to provide pressure sensors in the inflatable member to monitor the pressure of the balloon and control the infusion/exhaust of a fluid to maintain a desired pressure at the balloon.

To have provided the Saab device, as modified by the teachings of Campbell et al and Burton et al, with pressure sensors for monitoring and maintaining the balloon at a desired inflation pressure would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Abele et al.

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) as applied to claims 50 and 53 above, and further in view of the teaching of Deslauriers et al ('678).

Stern et al disclose a short, rigid probe for the treatment of uterine tissue. As addressed previously, Stern et al provide an inflatable member at the end of the probe for delivering RF current to tissue to create lesions/ablate the uterine tissue. Stern et al fail to specifically teach that the probe is malleable.

Deslauriers et al disclose a balloon probe device which includes a probe shaft with an inflatable balloon at the distal portion just as in Stern et al. In particular, Deslauriers et al teach that it is advantageous to provide the shaft as a malleable member to facilitate its insertion into the body passage and to conform to the desired tissue site.

To have provided the Stern et al probe, as modified by the teaching of Saab, with a malleable shaft to facilitate its insertion into the uterine cavity and to conform to the shape of the desired treatment area would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Deslauriers et al.

Claims 39, 41-43 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) in view of the teaching of Saab ('392).

Stern et al discloses a probe device which includes an inflatable member disposed at the distal end of the probe. As addressed previously, the inflatable member includes RF energy means for providing ablative RF current to tissue. While Stern et al teach that the balloon member is inflated during treatment, there is no specific teaching that a fluid is continuously infused and ventilated to maintain a desired pressure in the balloon. Rather, Stern et al simply inflate the balloon to the desired pressure and maintain the fluid within the balloon until the procedure is complete.

Saab discloses another system which includes a probe body with an inflatable member disposed at the distal end of the probe. Saab teach the use of the inflatable member to transfer heat to tissue, and further specifically teach that a fluid may be

continuously infused and ventilated to maintain the balloon at a desired pressure (col. 7). Also, Saab teaches that it is advantageous to provide a circulating cooling fluid to inflate the balloon while an alternative energy source is used to heat the tissue (col. 11). The examiner maintains that the Saab balloon does cause heating of tissue in that the heating member is located therein (see previous 35 USC 103 rejection).

To have provided the Stern et al balloon with means to provide continuous infusion and ventilation of a cooling fluid to enhance the heating effect of the RF treatment means would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Saab.

Claims 44 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) and further in view of the teaching of Deslauriers et al ('678).

The combination of the Saab teaching with the Stern et al device has been addressed previously. Neither of these references specifically teaches of a malleable probe body to facilitate insertion of the device into a body cavity.

Deslauriers et al disclose a balloon device which includes a probe shaft with an inflatable balloon at the distal portion similar to the Saab device. In particular, Deslauriers et al teach that it is advantageous to provide the shaft as a malleable member to facilitate its insertion into the body passage and to conform to the desired tissue site.

To have provided the Stern et al probe, as modified by the teaching of Saab, with a malleable shaft to facilitate its insertion into a body cavity and to conform to the shape of the desired treatment area would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Deslauriers et al.

Claims 46-48 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) and further in view of the teaching of Abele ('311).

The combination of the Saab teaching with the Stern et al device as been addressed previously. While Saab provides a means to continuously infuse and ventilate a cooling fluid into a balloon to maintain a desired pressure (col. 7, lines 5-20), there is no disclosure of using a pressure sensor to determine the pressure in the balloon and control the delivery of fluid to maintain a desired pressure.

Abele et al disclose an analogous device which includes a probe having an inflatable member at the distal end and means for effecting thermal transfer to tissue via the inflatable member. More specifically, Abele et al teach that it is known to provide pressure sensors in the inflatable member to monitor the pressure of the balloon and control the infusion/exhaust of a fluid to maintain a desired pressure at the balloon.

To have provided the Stern et al device, as modified by the teaching of Saab, with pressure sensors for monitoring and maintaining the balloon at a desired inflation pressure would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Abele et al.

Claims 45 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) and further in view of the teaching of Qian ('028).

As addressed previously, Stern et al disclose a balloon apparatus which includes means for providing RF current to tissue in order to ablate the treatment tissue. Saab further discloses the known use of circulating a cooling fluid to enhance the effects of a heat treatment catheter. Neither reference discloses a porous balloon which allows for the perfusion of a conductive fluid to tissue to enhance RF treatment of tissue.

The Qian device is substantially analogous to the Stern et al device in that it is a probe with an inflatable member which includes means to deliver RF current for the treatment of tissue. In particular, Qian teaches that it is known to provide the balloon with micropores which allows a certain amount of conductive fluid to be perfused to the tissue site to enhance the effect of the RF energy being delivered to tissue.

To have provided the Stern et al device, as modified by the teaching of Saab, with a porous balloon to allow a portion of the conductive fluid to perfuse tissue and enhance the delivery of RF energy to tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Qian.

Allowable Subject Matter

Claims 1, 3, 4, 6-16, 18-28, 33, 36, 37 and 49 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments with respect to claims 39 and 41-62 have been considered but are moot in view of the new ground(s) of rejection.

With respect to the Saab reference, applicant contends that the Saab therapeutic element (i.e. balloon) does not "cause tissue to be heated". The examiner disagrees. As is generally known in the art, and shown in Campbell et al and Burton et al, heating members for such devices are located within the balloon. The examiner deems that such an association causes heat to emanate from the balloon and therefore, the balloon is causing tissue to be heated.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brown et al ('320) discloses yet another balloon device which provides a cooling fluid to a balloon which otherwise provides heat energy to tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

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March 5, 2004